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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/885,287	06/21/2001	Andreas Sewing	MERCK-2261	2670

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EXAMINER	
GOLLAMUDI, SHARMILA S	
ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 03/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/885,287	Applicant(s) SEWING ET AL.	
	Examiner Sharmila S. Gollamudi	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10 and 21* is/are pending in the application.

4a) Of the above claim(s) *11-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-10 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Restriction Requirement and Request for an Extension of Time received on November 26, 2002 are acknowledged. Claims 1-10 and 21 are included in the prosecution of this application. Claims 11-20 are withdrawn from consideration.

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-10 and 21 in Paper No. 8 is acknowledged. The traversal is on the ground(s) that search of all the claims would not be undue burden since all relate to a coating for metallic implants. This is not found persuasive because as invention I and II are distinct because they are related as a coating composition and a method of coating via a electrochemical process. The coating composition may be applied to the implant via different processes (dipping or spraying) other than instantly claimed process. Further, the electrochemical method of coating an implant does not require the composition of invention I.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites "wherein collagen matrix is layered." It is unclear what exactly the collagen matrix is layered on. Further clarification is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 5-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Sauk et al (4,780,450).

Sauk et al disclose a composition containing particulate calcium phosphate (hydroxyapatite) and type I collagen (col. 4, lines 59-66). A mixture of type I and type III collagen is taught (example 1).

*Note that the recitation "for metallic implant materials" is intended use and is not given patentable weight.

Claims 1-3 and 5-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Geistlich et al (5,573,771).

Geistlich et al disclose a bone mineral product containing bone, collagen, and gelatin (examples and claims 1 and 8). The reference discloses that the natural bone used contains calcium phosphate, brushite, whitlockite, and octa-calcium phosphate (col. 1, lines 30-31). Type I or a mixture of type I-III is taught (col. 2, lines 41-43).

Claims 1-3, 5, and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Rhee et al (5,543,441).

Rhee et al teach implants coated with collagen-polymer conjugates. The composition contains collagen (Type I) and hydroxyapatite or gelatin beads (example 7).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Geistlich et al (5,573,771).

Geistlich et al disclose a bone mineral product containing bone, collagen, and gelatin (examples and claims 1 and 8). The reference discloses that the natural bone used contains calcium phosphate, Brushite, whitlockite, and octa-calcium phosphate (col. 1, lines 30-31). Type I or a mixture of type I-III is taught (col. 2, lines 41-43). The reference teaches the inclusion of instant actives to destroy bacteria and aid in bone regeneration (col. 3, lines 20-60).

Geistlich et al do not exemplify the inclusion of the active agent.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include an active agent into the composition. One would be motivated to do so since as taught by Geistlich, these actives can kill bacteria or encourage bone regeneration.

Claims 1-3, 5, 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rhee et al (5,543,441).

Rhee et al teach implants coated with collagen-polymer conjugates. The composition contains collagen-polymer conjugates with hydroxyapatite for the repair of stress-bearing bone due to its high tensile strength (col. 6, lines 42-46). The composition may also include growth factors to encourage growth and heal wounds (col. 6, lines 46-62). The composition may be coated on a titanium implant (example 5).

Rhee et al does not exemplify the active agent in the composition or using the collagen and hydroxyapatite for coating the implant.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to coat the metal implant with the instant coating of collagen and hydroxyapatite. One would be motivated to do so since Rhee et al teaches the use of instant composition to coat the implant since it is useful the repair of stress-bearing bone due to its high tensile strength.

Claims 1-4, 9-10, 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shirkanzadeh (5,205,921).

Shirkanzadeh teaches a method of depositing bioactive coatings on conductive substrates. The substrate can be titanium or steel (col. 2, lines 17-18). The coating composition includes hydroxyapatite, instant doping agents, and collagen to produce the desired ceramic coating (col. 3, lines 5-20).

The reference does not exemplify the coated implant with collagen.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add collagen into the coating composition to coat the implant. One would be motivated to do so since Shirkanzadeh teaches the suitability of adding collagen into the composition depending on the desired ceramic.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can normally be reached on M-F (7:30-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on (703) 308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SSG

February 26, 2003

MICHAEL G. HARTLEY
PRIMARY EXAMINER